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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,234	12/09/2004	Robert John Watson	CELL-0285	3692

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EXAMINER	
O DELL, DAVID K	

ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,234	WATSON ET AL.	
	Examiner	Art Unit	
	David K. O'Dell, Ph.D.	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11 and 13-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11, 13-22 are pending in the current application.

2. This is application is a National Stage of PCT/GB03/00720 filed February 19, 2003, which claims priority to United Kingdom application 0203994.9 filed February 20, 2002.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(cyclooct(a/e)nyl)methyl)piperidin-4-yl)-3-phenylurea core, and where defined in applicant's Markush structure Formula 1, D is phenyl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is either 1-cyclooctene or cyclooctane, compounds and compositions possessing a 1-(1-(cyclooct(a/e)nyl)methyl)piperidin-4-yl)-3-(2-naphthyl)urea core, and where defined in applicant's Markush structure Formula 1, D is 2-naphthyl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is either 1-cyclooctene or cyclooctane, and compounds and compositions possessing a 1-(1-(cyclooct(a/e)nyl)methyl)piperidin-4-yl)-3-(2,3-dihydro-1H-inden-5-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is 2,3-dihydro-1H-inden-5-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is either 1-cyclooctene or cyclooctane shown as structures **I** in Figure 1.

Group II, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(tricyclo[3.3.1.1.^{3,7}]decanyl)methyl)piperidin-4-yl)-3-phenylurea core, and where defined in applicant's Markush structure Formula 1, D is phenyl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 1-tricyclo[3.3.1.1.^{3,7}]decane, compounds and compositions possessing a 1-(1-(tricyclo[3.3.1.1.^{3,7}]decanyl)methyl)piperidin-4-yl)-3-(2-naphthyl)urea core, and where defined in applicant's Markush structure Formula 1, D is 2-naphthyl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 1-tricyclo[3.3.1.1.^{3,7}]decane, and compounds and compositions possessing a 1-(1-(tricyclo[3.3.1.1.^{3,7}]decanyl)methyl)piperidin-4-yl)-3-(2,3-dihydro-1H-inden-5-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is 2,3-dihydro-1H-inden-5-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 1-tricyclo[3.3.1.1.^{3,7}]decane shown as structures **II** in Figure 1.

Group III, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)methyl)piperidin-4-yl)-3-phenylurea core, and where defined in applicant's Markush structure Formula 1, D is phenyl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl, compounds and compositions possessing a 1-(1-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)methyl)piperidin-4-yl)-3-(2-naphthyl)-urea core, and where defined in applicant's Markush structure Formula 1, D is 2-naphthyl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl, and compounds and compositions possessing a 1-(1-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)methyl)piperidin-4-yl)-3-(2,3-dihydro-1H-inden-5-yl)-urea core, and where defined in applicant's Markush structure Formula 1, D is 2,3-dihydro-1H-inden-5-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl, shown as structures **III** in Figure 1.

Group IV, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(cyclooct(a/e)nyl)methyl)piperidin-4-yl)-3-(thiophen-2-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is thiophen-2-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is either 1-cyclooctene or cyclooctane shown as structure **IV** in Figure 1.

Group V, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(tricyclo[3.3.1.1.^{3,7}]decanyl)methyl)piperidin-4-yl)-3-(thiophen-2-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is thiophen-2-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 1-tricyclo[3.3.1.1.^{3,7}]decane shown as structure **V** in Figure 1.

Group VI, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)methyl)piperidin-4-yl)-3-(thiophen-2-yl)-urea core, and where defined in applicant's Markush structure Formula 1, D is thiophen-2-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl, shown as structure **VI** in Figure 1.

Group VII, Claims 1-7, 9-11 drawn to compounds and compositions possessing a 1-(1-(cyclooct(a/e)nyl)methyl)piperidin-4-yl)-3-(pyridin-4-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is pyridin-4-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is either 1-cyclooctene or cyclooctane shown as structure **VII** in Figure 1.

Group VIII, Claims 1-7, 9-11 drawn to compounds and compositions possessing a 1-(1-(tricyclo[3.3.1.1.^{3,7}]decanyl)methyl)piperidin-4-yl)-3-(pyridin-4-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is pyridin-4-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 1-tricyclo[3.3.1.1.^{3,7}]decane shown as structure **VIII** in Figure 1.

Group IX, Claims 1-7, 9-11 drawn to compounds and compositions possessing a 1-(1-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)methyl)piperidin-4-yl)-3-(pyridin-4-yl)-urea core, and where defined in applicant's Markush structure Formula 1, D is pyridin-4-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl, shown as structure **IX** in Figure 1.

Group X, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(cyclooct(a/e)nyl)methyl)piperidin-4-yl)-3-(1,2,4-triazin-5-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is 1,2,4-triazin-5-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is either 1-cyclooctene or cyclooctane shown as structure **X** in Figure 1.

Group XI, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(tricyclo[3.3.1.1.^{3,7}]decanyl)methyl)piperidin-4-yl)-3-(1,2,4-triazin-5-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is 1,2,4-triazin-5-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 1-tricyclo[3.3.1.1.^{3,7}]decane shown as structure **XI** in Figure 1.

Group XII, Claims 1-11 drawn to compounds and compositions possessing a 1-(1-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)methyl)piperidin-4-yl)-3-(1,2,4-triazin-5-yl)urea core, and where defined in applicant's Markush structure Formula 1, D is 1,2,4-triazin-5-yl, R^1 is H, Alk^3 is CH_2, m is 1, n is 1, and E is 6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl, shown as structure **XII** in Figure 1, and others not delineated here subject to further restriction.

Groups XIII to XXIV claims 13-22 drawn to methods of treatment etc., limited in scope to a single invention I-XII.

Figure 1 has been provided to the applicant to aid election:

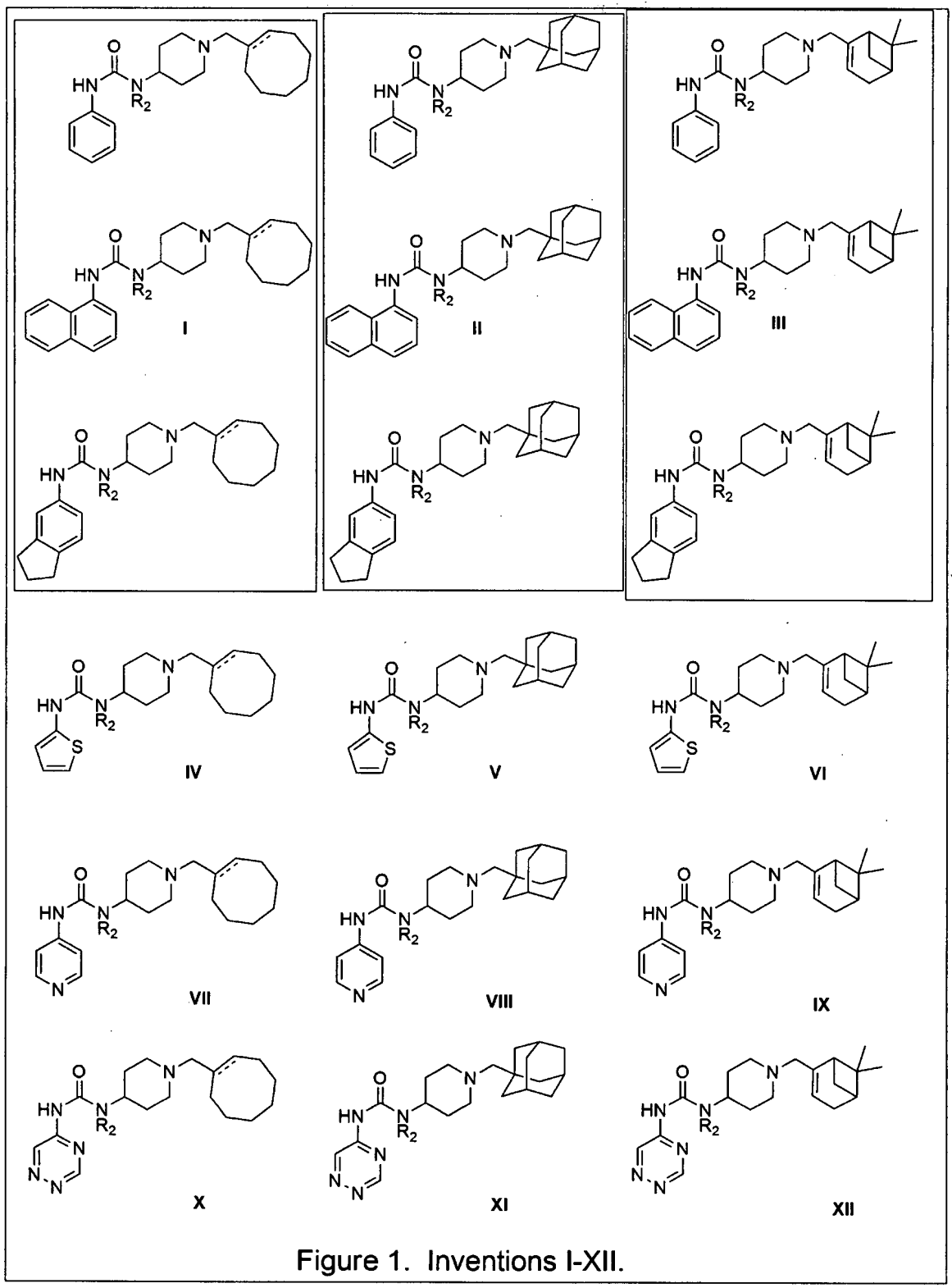


Figure 1. Inventions I-XII.

3. The inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

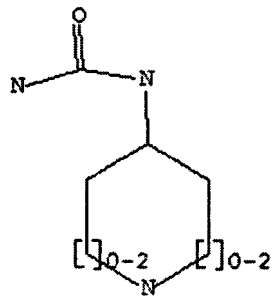
In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures,

the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables D, m, n, Alk3, E, R1, R2 etc. result in so many permutations giving both heterocyclic and non-hetero rings, different bonds between atoms, resulting in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, and reveals that up to 54,601 compounds bear this core see below:

```
L2      STRUCTURE UPLOADED

=> d 12
L2 HAS NO ANSWERS
L2                STR
```




```
Structure attributes must be viewed using STN Express query preparation.


=> s 12
SAMPLE SEARCH INITIATED 09:31:39 FILE 'REGISTRY'
SAMPLE SCREEN SEARCH COMPLETED -   119898 TO ITERATE

  1.7% PROCESSED     2000 ITERATIONS
INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)
SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS:  ONLINE  **INCOMPLETE**
                        BATCH   **INCOMPLETE**
PROJECTED ITERATIONS:      2377460 TO  2418460
PROJECTED ANSWERS:           48511 TO    54601
```

Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (3 7 CFR 1.143). **If Inventions X - XII or processes drawn to the use of said inventions is elected**, the applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that if Inventions **X - XII** or processes drawn to the use of said inventions are elected a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). **This requirement is not required for Inventions I-IX** or processes drawn to the use of said inventions.

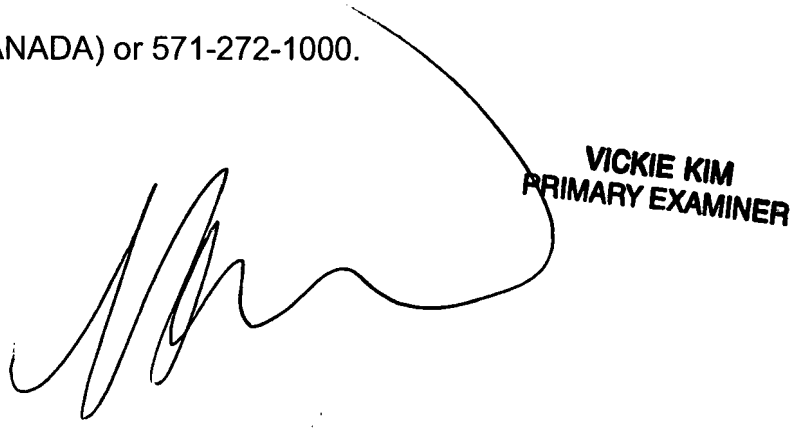
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell, Ph.D. whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.



VICKIE KIM
PRIMARY EXAMINER